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EXAMINER	
WITZ, J.	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 08/765,623	Applicant(s) Ruepp
	Examiner Jean C. Witz	Group Art Unit 1808

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-4 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Objections

1. Claim 4 is objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim may only refer to other claims in alternative. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

2. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd.

App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation of "egg-shells", and the claim also recites "especially from Gallus domesticus" which is the narrower statement of the range/limitation.

4. The term "elevated" in claim 1 is a relative term which renders the claim indefinite. The term "elevated" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

5. Claim 4 provides for the use of putamen ovi, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 4 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-4 are rejected under 35 U.S.C. 103(a) as obvious over EP 347899.

The claims are drawn to a method for preparing crushed eggshells where the eggshells are washed with purified water with stirring at room temperature or elevated temperature, subjected to an autoclave treatment, dried and crushed to desired grain size. The crushed eggshells obtained from this method and the use of same for pharmaceutical applications are also claimed.

EP 347899 discloses producing crushed eggshells for pharmaceutical compositions for treatment of mineral deficiency diseases where the eggshells are washed with pure water and the water is removed by centrifugation (Page 3, lines 13-17), the washed shells are dried with hot air at a temperature up to 150°C, advantageously a temperature from 60-120°C, followed by crushing the eggshells into a fine powder of a particle size of .010 mm to 0.080 mm. The crushed eggshells are then sterilized for about an hour at a temperature of about 120°C.

It is noted that autoclaving is a conventional sterilization method where substances are sterilized by steam for anywhere from 5 minutes to over an hour depending upon substance to be sterilized and the temperature and steam pressure used. See Cano and Colome, Microbiology, 1986, pages 158-159. It is noted at page 159, Table 7-2, that at 0 psi and 100°C,

the autoclave time is conventionally greater that 60 minutes; however, usual autoclave conditions are 121°C for 15-30 minutes at 15 psi. At page 161, hot air ovens are also conventional sterilization methods where the substance to be sterilized is exposed to hot air, usually at 160°C to 180°C for 1-2 hours.

Further, it is noted that Applicant defines the drying step as drying at increased temperatures and teaches that sterilizing step and drying step can be combined where the eggshells are dried at a temperature of at least 150°C for at least 3 hours.

Therefore, it would have been obvious to one of ordinary skill in the art wash eggshells in pure water, sterilize the eggshells via an autoclave treatment, dry the eggshells and crush them to a size of less than 0.1 mm as the prior art discloses a very similar process. The differences between the claims and the disclosure are that an autoclave treatment is not distinctly disclosed, that the sterilizations step, i.e. autoclaving, is performed after cleaning and before drying and crushing, the reference does not specifically set forth that the eggshells are ground with a pin-disk mill and that the composition has a grain size distribution as set forth in claim 3. As shown by the Cano and Colome reference set forth above and as stated by Applicant at page 5 of the specification, autoclaving is a conventional sterilization process use in the medical/pharmaceutical art, the selection of which is well within the skill of the practitioner especially in view of the parameters set forth by the reference, i.e. about an hour at about 120°C. As noted supra, Cano and Colome indicate that conventional autoclave conditions comprise times and temperatures of about an hour at about 120°C. See Table 7-2. Further, rearrangement of the steps is not seen as

conferring patentability to the process as it appears merely a choice of convenience and ease to sterilize the eggshells in the uncrushed form prior to crushing because the finely crushed powder would be more difficult to work with in a steam autoclave due to clumping and dispersion. Finally, in absence of evidence to the contrary, the use of a pin-disk mill is conventional when crushing a substance and as the prior art teaches that the eggshells are crushed to a size of between 0.010 and 0.080 mm, it would appear that the referenced composition would have a similar distribution, which has not been shown to be critical to the formulation of the crushed eggshells into pharmaceutical compositions.

It is noted at page 3 of the specification, it appears that Applicant addresses the EP 847899 references, but identifies it as EP 847859. There, Applicant states that "the sterilization of egg-shell powder with dry air at 120°C for about 1 hour is not suitable for effecting a safe reduction of pathogenic germs and to counteract a loss in active ingredients due to too high temperatures. An increase in temperature at [greater than] 80°C, especially in the range of [greater than or equal to] 150°C, for more than 1 hour destroys the biologically present carriers with membrane passage ability for an effective transport of minerals in compact and spongy substances. Following this thermal exposure, the egg-shell powder exhibits the biological effects of calcium carbonate with respect to the ^{45}Ca incorporation rate." However, Applicant at page 4 sets forth that "subsequent to the sterilization or optionally during the sterilization, the egg-shells are dried at elevated temperature" and at page 5, that "said germ count reduction or sterilization process is selected from autoclave treatment, hot air drying, tyndallization, treatment

with ionizing or non-ionizing radiation, and gas sterilization." Finally, the specification states that the drying step may encompass sterilization "especially at a temperature of at least 150°C, for at least 3 hours". As Applicant applies the same conditions to the egg-shells that the reference does, it is not seen, absent a side-by-side comparison, how Applicant's eggshell powder is effective and the referenced eggshell powder is not.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073.

August 11, 1997

JEAN C. WITZ
PRIMARY EXAMINER
GROUP 1800